COMMISSION REGULATION (EC) No 613/98

of 18 March 1998

amending Annexes II, III and IV of Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin [1], as last amended by Commission Regulation (EC) No 426/98 [2] and in particular Articles 6 and 8 thereof,

Whereas, in accordance with Regulation (EEC) No 2377/90, maximum residue limits must be established progressively for all pharmacologically active substances which are used within the Community in veterinary medicinal products intended for administration to food-producing animals;

Whereas maximum residue limits should be established only after the examination within the Committee for Veterinary Medicinal Products of all the relevant information concerning the safety of residues of the substance concerned for the consumer of foodstuffs of animal origin and the impact of residues on the industrial processing of foodstuffs;

Whereas, in establishing maximum residue limits for residues of veterinary medicinal products in foodstuffs of animal origin, it is necessary to specify the animal species in which residues may be present, the levels which may be present in each of the relevant meat tissues obtained from the treated animal (target tissue) and the nature of the residue which is relevant for the monitoring of residues (marker residue);

Whereas, for the control of residues, as provided for in appropriate Community legislation, maximum residue limits should usually be established for the target tissues of liver or kidney; whereas, however, the liver and kidney are frequently removed from carcasses moving in international trade, and maximum residue limits should therefore also always be established for muscle or fat tissues;

Whereas, in the case of veterinary medicinal products intended for use in laying birds, lactating animals or honey bees, maximum residue limits must also be established for eggs, milk or honey;

Whereas potassium nitrate, potassium dl-aspartate, potassium glucuronate and potassium glycerophosphate should be inserted into Annex II to Regulation (EEC) No 2377/90;

Whereas, in order to allow for the completion of scientific studies, florfenicol and moxidectin should be inserted into Annex III to Regulation (EEC) No 2377/90;

Whereas, in order to allow for the completion of scientific studies, the duration of the validity of the provisional maximum residue limits previously defined in Annex III of Regulation (EEC) No 2377/90 should be extended for albendazole sulphoxide and carprofen;

Whereas it appears that maximum residue limits cannot be established for metronidazole because residues, at whatever limit, in foodstuffs of animal origin might constitute a hazard to the health of the consumer; whereas it should be inserted into Annex IV to Regulation (EEC) No 2377/90;

Whereas a period of 60 days should be allowed before the entry into force of this Regulation in order to allow Member States to make any adjustment which may be necessary to the authorisations to place the veterinary medicinal products concerned on the market which have been granted in accordance with Council Directive 81/851/EEC [3], as last amended by Directive 93/40/EEC [4] to take account of the provisions of this Regulation;

Whereas the measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes II, III and IV of Regulation (EEC) No 2377/90 are hereby amended as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on the 60th day following its publication in the *Official Journal of the European Communities*.

[1] OJ L 224, 18. 8. 1990, p. 1.
[2] OJ L 53, 24. 2. 1998, p. 3.
[3] OJ L 317, 6. 11. 1981, p. 1.
[4] OJ L 214, 24. 8. 1993, p. 31.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 18 March 1998.

For the Commission

Martin BANGEMANN

Member of the Commission

ANNEX

A. Annex II is modified as follows:

1. Inorganic chemicals

Pharmacologically active substances(s)	Animal species	Other provisions
'Potassium nitrate	All food producing species	
Potassium DL-aspartate	All food producing species	
Potassium glucuronate	All food producing species	
Potassium glycerophosphate	All food producing species'	

B. Annex III is modified as follows:

1. Anti-infectious agents

1.2. Antibiotics

1.2.11. Florfenicol and related compounds

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Florfenicol	Sum of florfenicol and its metabolites measured as florfenicol-amine	Fish	1 000 µg/kg	Muscle and skin in natural proportions	Provisional MRLs expire on 1. 7. 2001'

2. Antiparasitic agents

2.1. Agents acting against endoparasites

2.1.1. Benzimidazoles and pro-benzimidazoles

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Albendazole sulphoxide	Sum of albendazole, albendazole sulphoxide, albendazole sulphone and albendazole 2-amino sulphone, expressed as albendazole	Bovine, ovine, pheasant	1 000 µg/kg	Liver	Provisional MRLs expire on 1. 1. 2000'
			500 µg/kg	Kidney	
			100 µg/kg	Muscle, fat	
		Bovine, ovine	100 µg/kg	Milk	

2.3. Agents acting against endo- and ectoparasites

2.3.1. Avermectins

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Moxidectin	Moxidectin	Equidae	50 µg/kg	Muscle	Provisional MRLs expire on 1. 1. 2000'
			500 µg/kg	Fat	
			100 µg/kg	Liver	
			50 µg/kg	kidney	

4. Anti-inflammatory agents

4.1. Nonsteroidal anti-inflammatory agents

4.1.1. Arylpropionic acid derivative

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Carprofen	Carprofen	Bovine	1 000 µg/kg	Liver, kidney	Provisional MRLs expire on 1. 1. 2000'
			500 µg/kg	Muscle, fat	
		Equidae	1 000 µg/kg	Liver, kidney	
			50 µg/kg	Muscle	
			100 µg/kg	Fat	

C. Annex IV is modified as follows:

List of pharmacologically active substances for which no maximum levels can be fixed

'Metronidazole.'